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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/006,492

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Lawrence R. Toll

SRE/4161-2

3231

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05/12/2005

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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,492

Applicant(s)

TOLL ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-75,77,78,80-108,111,112,114-140 and 142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-75,77,78,80-108,111,112,114-140 and 142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 2/28/05 have been fully considered but they are not persuasive.

Claims 72-75, 77-78, 80-108, 111-112, 114-140, and 142 are under consideration.

Claim Rejections - 35 USC § 101/112

Claims 72-75, 77-78, 80-108, 111-112, 114-140, and 142 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 72-75, 77-78, 80-108, 111-112, 114-140, and 142 are not originally filed claims.

Applicant has pointed to basis for these methods but this is not agreed with FOR AT LEAST the following reasons. The claims are now directed to a method for identifying similar biopolymers comprising constructing a statistical model, comparing the set of biopolymer sequences to the statistical model, and determining a likelihood that the set of biopolymer sequences is represented by the model and thereby similar biopolymers based on the score. While the specification discloses a method using an mHMM (the match Hidden Markov Model or integrated HMM) it does not contemplate a more general hidden Markov Model for identifying similar biopolymers. Limitations such as "set of known sequences that correspond to defined regions of a set of biopolymer sequences to provide characteristic topological pattern of match states...for a conserved region of the biopolymer sequences and...for a divergent region of the biopolymer sequences" are not supported. (See for example claims 72, 107, and 142.)

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While Figure 4 has a label for a conserved and divergent region of a particular protein, there are other states (“profile,” see also page 9 of the specification). Furthermore, the specification does not define what is considered conserved and divergent for a generic sequence. The hypothetical example in Figure 4 does not support or show contemplation of the more generic concept now claimed. The claim recites a first and second match state but Figure 4 shows more than two. The sections pointed to do not contemplate or define a “characteristic topological pattern of match states between the biopolymer sequences.” As set forth in the prior Office action, the claims embrace linking modules in any order and the modules are not required to reflect biological features. Again, the specification contemplates that the match state for each module is required to be one of similarity, dissimilarity, or matching to a profile. This is not reflected in the claims. As described by the specification, the match state is predicated on what is known or believed about the respective region (i.e. signal sequences should match a profile for a preprohormone, a known conserved region should require similarity for a preprohormone). The claims do not set forth these concepts.

Again with respect to claim 142, while a computer-readable medium having stored instructions which cause a processor to perform method steps is seen, the concept of a “plurality of instructions including” these instructions is not seen. Page 16 and Figure 7 do not disclose a plurality of instructions including the ones recited.

Claims 72-75, 77-78, 80-108, 111-112, and 114-140 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is maintained for reasons of record.

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Applicant appears to argue that the claims are statutory based on an output step. However, the recitation of “to provide an output score” cannot be construed as an output step but rather is a result of a computation. (See claims 72 and 107.) Note also that the determination of the likelihood that the set of biopolymer sequences is represented by the model and thereby similar biopolymers based on the score is not output either.

Applicant appears to argue that the claims are statutory by requiring “determining a likelihood that the set of biopolymer sequences is represented by the model and thereby similar biopolymers based on the score.” This is not considered to be a specific, concrete, and tangible result. Applicant argues that the comparison is to known, characterized sequences and can be used to assign function based on similarity. The claims have no steps or limitations to known, characterized sequences. They are directed to sequences of no known or specified function and sequences with no known conserved or divergent subregions.

Claims 72-75, 77-78, 80-108, 111-112, 114-140, and 142 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “and thereby similar biopolymers based on the score” is grammatically confusing and unclear. It appears that a word or a phrase may be missing.

Conclusion

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

A handwritten signature in cursive script that reads "Marianne P. Allen".

Marianne P. Allen

Primary Examiner

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mpa